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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.              | CONFIRMATION NO. |
|---|-------------|-----------------------|----------------------------------|------------------|
| 10/707,043  | 11/17/2003  | Richard M. Chesbrough | 289-PDD-07-31 US                 | 4168             |
| 69683   | 7590        | 08/06/2009            |                                  |                  |
| C. R. Bard, Inc.<br>Bard Peripheral Vascular, Inc.<br>1415 W. 3rd St<br>PO Box 1740<br>Tempe, AZ 85280-1740 |             |                       | EXAMINER<br>WEATHERBY, ELLSWORTH |                  |
|   |             |                       | ART UNIT                         | PAPER NUMBER     |
|   |             |                       | 3768                             |                  |
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|   |             |                       | 08/06/2009                       | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/707,043   | <b>Applicant(s)</b><br>CHESBROUGH ET AL. |  |
|                              | <b>Examiner</b><br>ELLSWORTH WEATHERBY | <b>Art Unit</b><br>3768                  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-47 and 48-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 6-26, 30-43, 47 and 49-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (Pub. No. 2001/0034528) in view of Makower et al. (USPN 6,090,063).

3. Foerster et al. teaches an apparatus which is capable of delivering a marker to a tissue mass, comprising: A trackable cannula defining a lumen and having a distal end forming an insertion tip [0002; 0047; 0054] and a localization wire [0011-0012; 0018-0019] located within the lumen and having a distal end near the insertion tip when the cannula is in the insertion position and an actuator in operable communication with the cannula and operable between a charged condition and a discharged condition to effect the relative movement of the cannula and the localization wire to expose the distal end of the localization wire to the tissue mass [0019]; wherein, to implant the localization wire into the tissue mass, the cannula is inserted into the tissue mass and the actuator is placed in the discharged condition to effect relative movement of the cannula and the localization wire and expose the distal end of the localization wire to the tissue mass [0018; 0054]. Foerster et al. also teaches using a sharpened insertion tip to aid in the insertion of the cannula into the tissue mass [0019]. Foerster et al. also teaches that the

localization wire comprises at least one anchor for holding the localization wire in the tissue mass and that the anchor extends beyond the distal end of the cannula when the actuator effects the relative movement of the cannula and the localization wire [0019].

Foerster et al. also teaches other embodiments where the marker element has blunt, rather than sharpened edges, but is adapted to expand sufficiently (or change contour) upon exiting from the tube that its edges press radially against the selected tissue, thereby wedging and implanting the marker element or providing integrally formed barbs to aid in the positioning of the marker coil [0019; 0059].

4. Foerster does not expressly teach that an actuator is operable to retract the cannula. Foerster also does not expressly teach that the actuator retracts the cannula relative to the localization wire from an insertion position to an implant position to effect the relative movement of the cannula and localization wire and expose the distal end of the localization wire. Foerster et al. also does not expressly teach that the actuator comprises a slide that is manually moved by the user from the charged to the discharged condition to retract the cannula relative to the localization wire. Foerster et al. also does not expressly teach the actuator comprises a slide that is automatically moved from the charged to the discharged condition to retract the cannula relative to the localization wire. Foerster also does not expressly teach a handle or a grip. Foerster also does not expressly teach that the biasing element is a spring.

5. In a related field of endeavor, Makower et al. teaches the deployment of a localization filament (abstract). Makower et al. goes on, teaching the use of an actuator in operable communication with an insertion cannula to retract the cannula to expose

the distal end of the localization wire, comprising an anchor, to the tissue mass where the actuator further comprises a spring (col. 2, l. 63- col. 3, l. 37; col. 9, ll. 7-60; col. 11, ll. 10-25; claim 7). Makower further teaches a trigger operable between a ready position and a release position on a handle with a grip for controlling the operation of the biasing element (Fig. 5; Fig. 15B).

6. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the localization wire deployment of Foerster in view of the actuator in operable communication with the cannula of Makower. The motivation to modify Foerster in view of Makower would have been to deploy the localization in combination with the removal of the insertion device thereby reducing the necessary steps and improving speed or ease of use.

7. Claims 27-29 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al. (Pub. No. 2001/0034528) in view of Makower et al. (USPN 6,090,063) as applied to claim 25 above, and further in view of Truckai et al. (USPN 6,813,520).

8. The localization wire insertion device of Foerster in view of Makower teaches all the limitations of the claimed invention except for expressly teaching that the trigger is pivotally mounted to the handle and includes a finger (or key) that abuts the collar (or keyway) when the trigger is in the ready position, and can be pivoted to the release position to remove the finger from abutting contact with the collar to release the spring.

9. Truckai et al. teaches a handle defining a hollow interior and an end, with the cannula being slidably mounted to the end wherein the handle comprises a base and a grip, with the grip being slidably mounted to the base for movement between a first position, where the cannula and an internal device are substantially received within the grip, and a second position, where the cannula and localization wire are substantially exteriorly of the grip (col. 7, l. 52- col. 8, l. 7). Truckai et al. also teaches providing a spring that is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position or that it is disposed between the base and the grip and the spring is compressed when the grip is moved to the second position (col. 8, ll. 8-28). Truckai et al. further teaches a locking mechanism that may be provided to hold the shaft in the fully withdrawn condition to prevent inadvertent closure of the spring members during the procedure (col. 8, ll. 28-32).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the localization wire insertion device of Foerster in view of Makower with the handle grip key and keyway of Truckai et al. The motivation to modify Foerster in view of Makower with Truckai et al. would have been to use a well known method that allows simple and safe manipulation of a device's distal tip by the user operating the device from the proximal end, as taught by Truckai et al.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-4, 6-47 and 48-75 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768